

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

WAVE NEUROSCIENCE, INC.,

Plaintiff,

vs.

BRAIN FREQUENCY LLC,

Defendant.

Civil Action No. 5:23-cv-00626-XR

Demand for Jury Trial

**DEFENDANT BRAIN FREQUENCY LLC'S MOTION FOR PARTIAL SUMMARY
JUDGEMENT PURSUANT TO THE PHYSICIAN'S IMMUNITY STATUTE**

Pursuant to Rule 56 of the Federal Rules of Civil Procedure, Defendant Brain Frequency LLC ("Brain Frequency") hereby moves for summary judgment that it is immune from any allegations of direct or induced infringement as to all method claims asserted by Plaintiff Wave Neuroscience LLC ("Plaintiff") pursuant to 35 U.S.C. § 287(c)(1), known as the "Physician's Immunity Statute." In support thereof, Brain Frequency would respectfully show the Court as follows:

I. INTRODUCTION

Section 287(c) of the Patent Act, known as the Physician's Immunity Statute, mandates an exception to infringement claims asserted under Section 271 (a) and (b) of the Patent Act. In cases where infringement allegations involve medical practitioners or physicians performing medical procedures on patients in violation of an asserted method claim, these parties are *immune from all remedies associated with the alleged infringement*. The Physician's Immunity Statute also broadly extends this immunity to "related health care entities" (*i.e.* Brain Frequency) that assist physicians or medical practitioners in performing such medical procedures.

The vast majority of claims asserted in this litigation against Brain Frequency are method claims that relate to the performance of a medical procedure by medical practitioners on patients, and thus providing immunity from all remedies associated with the alleged infringement. Because Brain Frequency is a “related health care entity” that merely facilitates the performance of those accused medical activities by medical practitioners, it is immune. For these reasons, all of Plaintiff’s asserted method claims should be dismissed under the Physician’s Immunity Statute.

II. RELEVANT BACKGROUND

A. The Asserted Patents and Claims

Plaintiff alleges Brain Frequency infringes four patents in this case. [*See* Appendix A, Separate Statement of Undisputed Material Facts In Support of Brain Frequency’s Partial Motion for Summary Judgment Pursuant to the Physician’s Immunity Statute (“SUF”) at ¶¶ 1-3.] Three of those patents contain asserted method claims, including U.S. Patent Nos 10,029,111 (the “’111 Patent”); 8,465,408 (the “’408 Patent”); and 8,870,737 (the “’737 Patent”) (collectively the “Asserted Method Patents.”) [*Id.* at ¶¶ 1-4, 8, 22, 36.] On December 15, 2023, Plaintiff served its infringement contentions (“Infringement Contentions”) identifying its asserted claims for each of the Asserted Method Patents. [*Id.* at ¶ 4.]

With respect to the ‘111 Patent, entitled “RTMS At Harmonics of Biological Signals,” it teaches certain medical procedures and methods for treating patients. [*Id.* at ¶¶ 5, 9-14.] For example, Claim 1 teaches “A method of improving a physiological condition or a neuropsychiatric condition [] which comprises [] repetitive transcranial magnetic stimulation (rTMS) at a frequency of a non-EEG biological metric...” [*Id.* at ¶ 9.] Plaintiff alleges Brain Frequency infringes Claim 1 of the ‘111 Patent, which is an independent claim, and claims 3-7, which are dependent claims. [*Id.* at ¶¶ 6-7.] Each of these claims are method claims, and each limitation of the claims relate to

the performance of a medical activity or procedure by a medical practitioner. [*Id.* at ¶¶ 8-14.]

The '408 Patent, entitled "Systems and Methods For Modulating The Electrical Activity of a Brain Using Neuro-EEG Synchronization Therapy" also teaches certain medical procedures and methods for treating patients. [*Id.* at ¶¶ 18, 23-28.] For example, Claim 1 teaches "A method of treating Parkinson's disease...[by] adjusting a setting of a magnetic field....[to] move an intrinsic frequency of a specified EEG band of the subject toward a target intrinsic frequency of the specified EEG band using the magnetic field...." [*Id.* at ¶ 23.] Plaintiff alleges Brain Frequency infringes Claims 1 and 2 of the '408 Patent among others, which are independent claims, and Claims 3-4 and 9-10, which are dependent claims. [*Id.* at ¶¶ 19-21.] Each of these claims are method claims, and each limitation of the claims relate to the performance of a medical activity or procedure by a medical practitioner. [*Id.* at ¶¶ 22-28.]

The '737 Patent, entitled "Systems and Methods for Neuro-EEG Synchronization and Therapy," likewise teaches certain medical procedures and methods for treating patients. [*Id.* at ¶¶ 32, 37-42.] For example, Claim 1 teaches "adjusting [the] output of a magnetic field; applying said magnetic field close to a head of a subject; and moving, using the magnetic field, at least one of an intrinsic frequency of a specified EEG band of the subject toward a pre-selected intrinsic frequency...wherein the pre-selected intrinsic frequency is a frequency that increases blood flow in the cortex of the subject." [*Id.* ¶ 37.] Plaintiff alleges Brain Frequency infringes Claims 1 and 2 of the '737 Patent, which are independent claims, and Claims 3-4, 8-9, and 11, which are dependent claims. [*Id.* at ¶¶ 33-35.] Each of these claims are method claims, and each limitation of the claims relate to the performance of a medical activity or procedure by a medical practitioner. [*Id.* at ¶¶ 36-43.]

Plaintiff contends Brain Frequency is liable for direct and induced infringement of each of

the forgoing claims (the “Asserted Method Claims”) pursuant to Section 271(a) and (b) of the Patent Act. [*Id.* at ¶¶ 15-17, 29-31, and 44-46.]¹²

B. Brain Frequency and The Accused Software

Brain Frequency provides software technology to assist with the treatment of individuals suffering from mental disorders and other conditions, including trauma, post-traumatic stress disorder, addiction, depression and anxiety. [SUF at ¶ 47.] Brain Frequency’s founder, Shannon Malish, is a Licensed Clinical Social Worker (“LCSW”) in the State of Texas and has years of experience facilitating the treatment of patients suffering from such conditions. [*Id.* at ¶ 48.]

During her professional career, Ms. Malish’s treatments have included Transcranial Magnetic Stimulation (“TMS”), which is a widely-known therapy of providing magnetic stimulation to affected areas of the brain. [*Id.*] Recognizing that TMS—in combination with a patient’s EEG data—has historically provided positive results for mental therapy, Ms. Malish set out to improve the treatment method. [*Id.* at ¶ 49.] After years of clinical research, Ms. Malish discovered certain patterns in areas of the brain (as measured by EEG data) correlating to certain mental disorders. [*Id.*] Her efforts lead to the development of Brain Frequency’s proprietary software (hereinafter the “Brain Frequency Software”) which much more precisely analyzes a patient’s EEG measurements to more accurately indicate areas of the brain that are negatively

¹Neither Plaintiff’s Second Amended Complaint nor its Infringement Contentions contain any specific evidence or allegations of contributory infringement pursuant to Section 271(c). [SUF at ¶¶ 15-17, 29-31, and 44-46; *see also id.* at ¶ 4, Ex. 4.]

² Plaintiff also alleges that Brain Frequency infringes certain claims of United States Patent No. 8,926,490 (the “’490 Patent”) and Claims 12 and 20 of the ’408 Patent. Because these claims are apparatus claims, they are not subject to the Physician’s Immunity Statute, and thus Brain Frequency does not seek summary judgment as to these claims.

impacted.³ [*Id.* at ¶ 50.]

Brain Frequency licenses the Brain Frequency Software to individual medical practitioners or medical organizations that exclusively treat patients with mental disorders for the purpose of assisting these doctors and clinicians with more effective diagnosis and treatments. [*Id.* at ¶¶ 53.] Each of Brain Frequency’s licensees are medical practitioners or those acting under the direction and supervision of medical practitioners who are licensed by the State of Texas or other states. [*Id.* at ¶¶ 54-55.] Further, each of Brain Frequency’s medical practitioner licensees provide medical diagnosis or treatment to medical patients using the Brain Frequency Software pursuant to the contractual agreements entered into between Brain Frequency and the medical practitioners. [*Id.* at ¶¶ 56-57.] Indeed, each contractual agreement requires that: “All Users must be licensed and registered to practice medicine in the jurisdiction of the Permitted Location at which they use the Brain Frequency System or employed under the supervision of a professional who is so licensed and registered. All Users must have the requisite experience and skill to practice in the area of medicine and/or behavioral health within which they are using the Brain Frequency System.” [*Id.* at ¶ 56, Ex. 5 at Sec. 4.4.]

Pursuant to the contractual agreements between Brain Frequency and its licensees, the Brain Frequency Software is also intended to be used exclusively for the purpose of engaging in medical activities, namely, the diagnosis and treatment of medical patients. [*Id.* at ¶ 58.]

III. APPLICABLE LEGAL STANDARDS

A. The “Physician’s Immunity Statute” (35 U.S.C. § 287(c)(1))

Section 281 of the Patent Act provides that “[a] patentee shall have remedy by civil action

³ The Brain Frequency Software is the sole instrumentality alleged by Plaintiff to infringe each of the Asserted Method Claims addressed herein. [*See* SUF at ¶ 4.]

for infringement of his patent.” 35 U.S.C. § 281. Sections 283, 284, and 285 of the Patent Act provide the remedies for infringement, including injunctive relief, damages, and attorneys’ fees, respectively. [35 U.S.C. §§ 283–285.] However, Section 287(c)(1)— the Physician’s Immunity Statute—provides that “[w]ith respect to a medical practitioner’s performance of a *medical activity* that constitutes an infringement under section 271(a) or (b), the provisions of sections 281, 283, 284, and 285 . . . *shall not apply against the medical practitioner or against a related health care entity* with respect to such medical activity.” [35 U.S.C. § 287(c)(1) (emphasis added).]

In short, Section 287(c) was intended to protect physicians *and* related health care entities from infringement claims for certain medical procedures and methods used to treat actual patients. *See Emtel, Inc. v. Lipidlabs, Inc.*, 583 F. Supp. 2d 811, 822 (S.D. Tex. 2008). In the event a medical practitioner or related health care entity meets the elements for immunity and none of the limited exceptions to immunity apply, Section 287(c) precludes *all infringement liability* for those accused procedures and methods against the physician *or* the related health care entity. *Id.* at 818 (noting that “Section 287(c) is properly understood as an immunity provision . . . An immunity, unlike a privilege, avoids liability under all circumstances. It does not deny the injury but rather prevents any liability.”) (internal citations and quotations omitted).

B. Summary Judgment

A court must grant summary judgment if the record shows there is no genuine issue as to any material fact and the moving party is entitled to judgment as a matter of law. FED. R. CIV. P. 56(a); *Frederking v. Cincinnati Ins. Co.*, 447 F. Supp. 3d 577, 579 (W.D. Tex. 2020). The moving party bears the initial burden of informing the court of the basis for the motion and of identifying those portions of the record which demonstrate the absence of a genuine issue of material fact. *Id.*; *Adams v. Travelers Indem. Co.*, 465 F.3d 156, 163 (5th Cir. 2006). Once the moving party meets

this burden, the nonmoving party must “go beyond the pleadings” and “identify specific evidence in the record and articulate the manner in which that evidence supports that party’s claim.” *Johnson v. Deep E. Tex. Reg’l. Narcotics Trafficking Task Force*, 379 F.3d 293, 301 (5th Cir.2004) (citations omitted). “This burden is not satisfied with ‘some metaphysical doubt as to the material facts,’ by ‘conclusory allegations,’ by ‘unsubstantiated assertions,’ or by ‘only a “scintilla” of evidence.’” *See Emtel, Inc. v. Lipidlabs, Inc.*, 583 F. Supp. 2d 811, 827 (S.D. Tex. 2008) (citations omitted).

IV. ARGUMENTS AND AUTHORITIES

Section 287(c)(1) provides as follows:

With respect to a ***medical practitioner’s*** performance of a ***medical activity*** that constitutes an infringement under section 271(a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title ***shall not apply*** against the medical practitioner ***or against a related health care entity*** with respect to such medical activity.

35 U.S.C. § 287(c)(1) (emphasis added). As demonstrated herein, each of the Asserted Method Claims concern a “medical practitioner’s” performance of a “medical activity,” and therefore constitute a protected medical activity under Section 287(c). Moreover, Brain Frequency qualifies as “a related health care entity,” and is therefore entitled to the protections of Section 287(c). Finally, none of the exceptions to the application of Section 287(c) are applicable in this case. Accordingly, Brain Frequency is entitled to summary judgment as a matter of law.

A. The Asserted Method Claims All Require the Performance of a “Medical Activity” by a “Medical Practitioner”

Pursuant to Section 287(c), immunity applies to alleged infringement of a “medical activity” by a “medical practitioner.” 35 U.S.C. § 287(c)(1). “Medical practitioner” is defined under Section 287(c) to mean “any natural person who is licensed by a State to provide the medical activity described . . . or who is acting under the direction of such person in the performance of the

medical activity.” 35 U.S.C. § 287(c)(2)(B). The term “medical activity” is defined by the statute to mean “the performance of a medical or surgical procedure on a body” 35 U.S.C. § 287(c)(2)(A). Medical activity also broadly includes actions such as “[d]iagnosing a medical condition, providing instructions to a different medical caregiver in a different location about treating that caregiver’s patient, and aiding another caregiver in treating a patient’s medical condition.” *See Emtel*, 583 F. Supp. at 824 (emphasis added).

As demonstrated in Brain Frequency’s Statement of Undisputed Material Facts filed herewith, each limitation of the Asserted Method Claims relate to “the performance of a medical or surgical procedure on a body” by a “medical practitioner.” [See Section II.A., *supra*; see also SUF at ¶¶ 9-14, 23-28, and 37-43.] Accordingly, the activities disclosed in the Asserted Method Claims are subject to the immunity provisions of Section 287(c). 35 U.S.C. § 287(c)(1).

B. Brain Frequency is a “Related Health Care Entity” with Respect to a “Medical Activity” Provided to a “Medical Practitioner”

Section 287(c) extends immunity to “related health care entities.” 35 U.S.C. § 287(c)(1). Section 287(c)(2)(C) broadly defines a “related healthcare entity” as “an entity with which a medical practitioner has a *professional affiliation* under which the medical practitioner performs the medical activity, including but not limited to a . . . hospital, university, medical school, health maintenance organization, group medical practice, or a medical clinic.” 35 U.S.C. § 287(c)(2)(C) (emphasis added). As used in Section 287(c)(2)(C), the term “professional affiliation” includes “staff membership, . . . *contractual relationship*, . . . or *other affiliation under which a medical practitioner provides the medical activity on behalf of, or in association with, the health care entity*.” 35 U.S.C. § 287(c)(2)(D) (emphasis added).

Here, Brain Frequency maintains contractual relationships and associations with medical practitioners under which the practitioners provide medical diagnosis and treatment of patients

facilitated, in part, by Brain Frequency. [See Section II.B., *supra*; see also SUF at ¶¶ 51-58.] Specifically, each of Brain Frequency’s medical practitioners provide medical diagnosis or treatment to patients using the Brain Frequency Software pursuant to a contractual license agreement. [*Id.* at ¶¶ 56-58.] Thus, Brain Frequency maintains a “professional affiliation” with “medical practitioners” and is therefore a “related health care entity” under Section 287(c).

Federal Courts in this State have found that that companies providing videoconferencing services to physicians under contract to facilitate medical services qualify as “related health care entities” under Section 287(c). In *Emtel*, the U.S. District Court for the Southern District of Texas found that movant defendants, who merely provided “business, administrative, and technological support to their affiliated physicians, as well as videoconferencing equipment,” qualified as “related health care entities.” *Emtel*, 583 F. Supp. at 817 (noting that the physicians were “independent contractors who exercised independent judgment and maintained discretion over the medical care they provided to patients”). Even though movants did *not* provide the actual medical treatment or diagnosis themselves, their agreements and relationships with independent contractor physicians qualified them as “related health care entities.” *Emtel*, 583 F. Supp. at 824-25.

The same is true here. Brian Frequency has license agreements with physicians and practitioners to perform the medical treatment using the Brain Frequency Software. [SUF at ¶¶ 51-58.] Accordingly, Brain Frequency qualifies as a “related health care entity” under Section 287(c) because of its relationship with medical practitioners to facilitate treatment of patients.

C. The Limited Exemptions Precluding Application of Immunity Under Section 287(c) Do Not Apply to Brain Frequency

While the Physician’s Immunity Statute provides protection for the performance of certain medical activities, those protections do not apply where the infringement allegations involve (1) *the use of a patented machine*, manufacture, or composition of matter, (2) the practice of a

patented composition of matter, or (3) violation of a biotechnology patent. *See* 35 U.S.C. § 287 (c)(2)(A) (emphasis added). While Section 287 itself does not provide a definition of a “biotechnology patent,” the legislative history of the statute explains the intended meaning:

[F]or the purposes of this provision the definition of the term “biotechnology patent” includes ... a patent on a process of making or using biological materials, including treatment using those materials, where those materials have been manipulated . . . at the cellular or molecular level . . . Cellular substances include (but are not limited to) cultured microbial and mammalian cells

See Vetstem Biopharma, Inc. v. California Stem Cell Treatment Ctr., Inc., No. CV 19-04728 AB (FFM), 2019 WL 8221083, at *2 (C.D. Cal. Oct. 31, 2019).

Here, each of the asserted claims subject to this motion are method claims, and by their very nature, do not involve “use of a patented machine.” [SUF at ¶¶ 8, 22, and 36.]⁴ Further, none of the asserted claims involve a practice of a patented composition of matter (*e.g.* pharmaceuticals), nor do any of the Asserted Method Patents constitute a “biotechnology patent.” [*Id.* at ¶¶ 5-14, 23-28, 37-43, and 59.] Accordingly, the exemptions from immunity in Section 287 (c)(2)(A) do not apply.

Section 271(c) also does not apply where the medical activities at issue are (1) directly related to the commercial development, manufacture, sale, importation, or distribution of ***a machine, manufacture, or composition of matter or clinical laboratory services***; **and** (2) regulated under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act. 35 U.S.C. § 287(c)(3) (emphasis added). Here, ***neither*** prong applies to Brain Frequency.

⁴ This is the reason that immunity does not apply to apparatus claims which do involve use of a patented device.

With regard to the former, commercial development activities—such as marketing, promotion, and advertising activities of a product for commercial gain— are not protected by Section 287(c). However, merely providing educational information such as “instructions to a medical caregiver about a patient” or “aiding the treatment of a medical condition” **are** protected. *See Emtel*, 583 F. Supp. 2d at 820, 823.

Plaintiff alleges in its Amended Complaint that “Brain Frequency actively promotes the commercial development of Brain Frequency’s technology and methods,” and cites to a podcast appearance by Brain Frequency’s founder and to a YouTube video on Brain Frequency’s website. [See Dkt. No. 10 at ¶ 35; *see also id.* FN 9-11.] Notably, the Brain Frequency software referred to in the Podcast and YouTube video is not a “machine, manufacture, or composition of matter or clinical laboratory service[],” and for that reason alone, the exception does not apply. 35 U.S.C. § 287(c)(3). [SUF at ¶ 59.] Moreover, the information provided by Brain Frequency in the Podcast and YouTube video identified by Plaintiff do not relate to advertising or marketing at all, but instead are entirely related to providing educational information to medical professionals and others regarding diagnosis and treatment of patients with certain medical conditions. [*Id.* at ¶¶ 62-63.]⁵

Finally even assuming, *arguendo*, that the alleged evidence cited in Plaintiff’s Amended Complaint could be construed as commercial promotion instead of the exchange of medical information (it cannot), Section 287(c)(3) nevertheless still does **not** apply. As noted above, the exemption requires commercial development or promotion of a product **that is also** “regulated”

⁵ It is notable that Plaintiff cites to an entire hour-long podcast and a long YouTube video as “evidence” of commercial promotion without providing a specific instance via timestamp of any actual advertising or marketing for commercial gain. [See Dkt. No. 10 at ¶ 35.] This is because there is no such activity in either the video or the podcast.

by the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, or the Clinical Laboratories Improvement Act. 35 U.S.C. § 287(c)(3). The Brain Frequency Software is not regulated by any of the foregoing agencies. [SUF at ¶¶ 60-61.]⁶

V. CONCLUSION

For the reasons set forth herein, Defendant Brain Frequency respectfully requests the Court grant summary judgment that Brain Frequency is immune from all liability related to the alleged infringement of all of the Asserted Method Claims as a matter of law.

Dated: May 3, 2024

Respectfully submitted,

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⁶ In its Amended Complaint, Plaintiff's only reference to any regulatory body is that "The equipment used in Brain Frequency's treatments is regulated by the FDA according to Brain Frequency's website." [See Dkt. No. 10 at ¶ 35.] First, the FDA is not included in the exemption in Section 287(c)(3). Second, Brain Frequency does not provision or sell equipment, much less equipment regulated by federal law. Brain Frequency licenses software. Plaintiff cannot provide any proof that this software is regulated by the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, the Clinical Laboratories Improvement Act, or the FDA, because it is not. [SUF at ¶¶ 60-61.]

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CERTIFICATE OF SERVICE

I hereby certify that on May 3, 2024, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

/s/ John Saba
John D. Saba, Jr.